

REMARKS**Formal Matters**

Claims 1-53 and 55-63 are pending after entry of the amendments set forth herein. Claim 54 has been canceled without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

Please replace claims 4, 6-9, 11-14, 16, 19, 22-24, 26-29, 31-36, 38, 40, 47, 49-51, 55, 56, 60, 62 and 63 with the clean version provided above. These claims have been amended solely for the purpose of eliminating multiple dependencies to reduce filing costs. As such, the above amendments do not narrow the remaining claims within the meaning of Festo.

A substitute specification has been filed along with this amendment to amend this application to include headings consistent with U.S. practice and to amend the Abstract (a clean copy of which is also included with the substitute specification). No new matter has been presented by the substitute specification and a marked up copy of the original specification indicating the changes made by the substitute specification has also been included. Accordingly, the Examiner is respectfully requested to indicate entry of the substitute specification and Abstract in the next Official Action.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Applicants respectfully request reconsideration of the application in view of the substitute specification, amendments and remarks made herein.

No new matter has been added.

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Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number KEMP002.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date:

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By:



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Claim 4 was amended above as follows:

4. (Amended) A method of accelerating a dose of particles in a needleless injection device according to claim 1, [2 or 3,] further comprising producing a secondary shock wave travelling in a downstream direction behind said primary shock wave.

Claim 6 was amended above as follows:

6. (Amended) A method of accelerating particles according to [any one of the preceding claims claim 1, wherein said particles are entrained and accelerated from an initial position upstream of said closure means.

Claim 7 was amended above as follows:

7. (Amended) A method of accelerating particles according to [any one of the preceding claims] claim 1, wherein said particles are not accelerated through a constriction downstream of said closure means.

Claim 8 was amended above as follows:

8. (Amended) A method of accelerating particles according to [any one of the preceding claims] claim 1, wherein said closure means is a first closure means and the method further comprises opening a further closure means before opening said first closure means.

Claim 9 was amended above as follows:

9. (Amended) A method of accelerating particles according to [any one of the preceding claims] claim 1, further comprising directing said quasi-steady flow of fluid through a divergent nozzle positioned downstream of said duct section.

Claim 11 was amended above as follows:

11. (Amended) A method of accelerating particles according to claim 9 [or 10], wherein said quasi-steady flow directed through said nozzle portion exits the downstream end of said device with a velocity distribution that is substantially uniform over a cross-section thereof.

Claim 12 was amended above as follows:

12. (Amended) A method of accelerating particles according to [any one of claims] claim 9, [10 or 11,] wherein said divergent nozzle portion has an internal contour such that substantially no oblique shocks are formed in the part of said quasi-steady flow in which said particles are entrained.

Claim 13 was amended above as follows:

13. (Amended) A method of accelerating particles according to [any one of claims] claim 9 [to 12], further comprising spacing said needleless injection device from a target plane;
 creating a substantially normal shock wave at the exit of said divergent portion;
 decelerating the particles in said substantially normal shock wave so as to have a generally radially uniform velocity as they impact the target plane.

Claim 14 was amended above as follows:

14. (Amended) A method of accelerating particles according to [any one of claims] claim 9 [to 13], further comprising the step of initiating a (*u-a*) wave at the downstream end of said duct section.

Claim 16 was amended above as follows:

16. (Amended) A method of accelerating particles according to [any one of the preceding claims] claim 1, further comprising creating an expansion wave which travels in an upstream direction from the location of said closure means.

Claim 19 was amended above as follows:

19. (Amended) A method of accelerating particles according to {any one of the preceding claims] claim 1, further comprising the step of selecting the driver gas species, or combination of species, so as to control the velocity of the particles as they exit the device.

Claim 22 was amended above as follows:

22. (Amended) A needleless injection device according to claim 20 [or 21], wherein said closure means is positioned at the downstream extent of said driver chamber.

Claim 23 was amended above as follows:

23. (Amended) A needleless injection device according to [any one of claims] claim 20 [to 22], wherein said driver chamber is pre-charged with pressurised gas.

Claim 24 was amended above as follows:

24. (Amended) A needleless injection device according to [any one of claims] claim 20 [to 22], further comprising a source of gaseous fluid, said driver chamber being fluidly connected to said source and arranged to be provided with said charge of pressurised gas by said source upon opening of the fluid connection therebetween.

Claim 26 was amended above as follows:

26. (Amended) A needleless injection device according to [any one of claims] claim 20 [to 25], wherein said duct section comprises a tube of substantially constant cross-sectional area.

Claim 27 was amended above as follows:

27. (Amended) A needleless injection device according to [any one of claims] claim 20 [to 26], in which said particles are positioned upstream of said closure means.

Claim 28 was amended above as follows:

28. (Amended) A needleless injection device according to [any one of claims] claim 20 [to 27], wherein said duct section includes substantially no convergent portion therein downstream of said closure means.

Claim 29 was amended above as follows:

29. (Amended) A needleless injection device according to [any one of claims] claim 20 [to 28], further comprising a divergent nozzle portion positioned downstream of said duct section.

Claim 31 was amended above as follows:

31. (Amended) A needleless injection device according to claim 29 [or 30], wherein said divergent nozzle portion has an internal contour such that substantially no oblique shock waves are formed in said substantially quasi-steady flow.

Claim 32 was amended above as follows:

32. (Amended) A needleless injection device according to [any one of claims] claim 29 [to 31], wherein said divergent nozzle portion is contoured such as to cause any expansion downstream of the duct section to provide a generally radially uniform particle distribution at the exit of the divergent portion and a generally radially uniform particle velocity distribution, with a substantially parallel velocity of particles and gas exiting the device.

Claim 33 was amended above as follows:

33. (Amended) A needleless injection device according to [any one of claims] claim 29 [to 32], further comprising a spacer positioned at the downstream end of the device, the spacer being constructed so as to space a target plane downstream of the divergent nozzle portion exit with a clearance sufficient to allow:

a substantially normal shock wave to be positioned downstream of the exit of said divergent nozzle portion; so that

said normal shock interacts, in use, with the gas and particle jet from said device to provide a substantially controlled and uniform gas stagnation region which decelerates the particles to a generally uniform velocity as they impact the target plane.

Claim 34 was amended above as follows:

34. (Amended) A needleless injection device according to [any one of claims] claim 20 [to 37], wherein said driver chamber comprises a substantially constant area tube.

Claim 35 was amended above as follows:

35. (Amended) A needleless injection device according to [any one of claims] claim 20 [to 34], wherein said driver chamber comprises a convergence at its downstream end, positioned upstream of said closure means.

Claim 36 was amended above as follows:

36. (Amended) A needleless injection device according to [any one of claims] claim 20 [to 35], wherein said closure means comprises a rupturable membrane arranged to open by rupturing.

Claim 38 was amended above as follows:

38. (Amended) A needleless injection device according to [any one of claims] claim 20 [to 37], wherein said device contains a further closure means.

Claim 40 was amended above as follows:

40. (Amended) A needleless injection device according to claim 38 [or 39], wherein said further closure means comprises a rupturable membrane arranged to open by rupturing.

Claim 47 was amended above as follows:

47. (Amended) A particle retention assembly according to claim 45 [or 46], further comprising transfer duct closure means in said transfer duct.

Claim 49 was amended above as follows:

49. (Amended) A particle retention assembly according to [any one of claims] claim 45 [to 48], wherein said transfer duct is positioned in said second closure means.

Claim 50 was amended above as follows:

50. (Amended) A particle retention assembly according to [any one of claims] claim 42 [to 49], further comprising a dose of particles located between said first and second closure means.

Claim 51 was amended above as follows:

51. (Amended) A particle retention assembly according to [any one claims] claim 42 [to 50], wherein some or all of said various closure means are each constituted by a rupturable membrane which is scored or indented to provide controlled rupturing.

Claim 55 was amended above as follows:

55. (Amended) A needleless injection device comprising the assembly of [any one claims] claim 42 [to 54].

Claim 56 was amended above as follows:

56. (Amended) A method of needleless injection involving the injection of particles into bodily tissue, the method comprising accelerating the particles in a needleless injection device using the method of particle acceleration claimed in[any one claims] claim 1 [to 19].

Claim 60 was amended above as follows:

60. (Amended) A method of entraining a dose of particles according to claim 58 [or 59], further comprising providing a transfer duct closure means in said transfer duct.

Claim 62 was amended above as follows:

62. (Amended) A method of entraining a dose of particles according to [any one claims] claim 58 [to 61], further including the steps of allowing gas to pass through a small aperture in said upstream closure means; and

causing said upstream closure means to rupture after some gas has passed therethrough into said space between said upstream and downstream closure means.

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Claim 63 was amended above as follows:

63. (Amended) A method of needleless injection involving the injection of particles into bodily tissue, the method comprising entraining the particles in a gas flow in a needleless injection device using a method of particle entrainment according to [any one claims] claim 58 [to 62].